K061435

JUN - 8 2006

Applicant: Medela AG, Laettichstrasse 4b, CH-6341 Baar, Switzerland
Contact Person: Werner Frei, Tel +41 (41) 769 51 51 ext. 228; Fax +41 (41) 769 51 00
werner.frei@medela.ch
Traditional 510(k) Submission for Medela® Vario 18 c/i Suction Pump

Section E - 510(k) Summary

This 510(k) summary for the **Medela® Vario Powered Suction Pumps** meets the requirements of 21 CFR 807.92.

1 Sponsor's Name, Address and Contact Person

Sponsor:
Medela AG
Medical Equipment
Laettichstrasse 4b
6341 Baar
Switzerland
Ph: +41 41 769 5151 ext. 228
Fax: +41 41 769 5100

Contact Person
Werner Frei
Manager Regulatory Affairs

Date Summary Prepared: February 16, 2006

2 Name of Device

Trade Name:	**Medela® Vario 8 and Vario 18** Secretion & Surgical Aspirator
Common Name:	Powered Suction Pump
Classification Name:	PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED) Classified Class II, per 21 CFR 878.4780
Product Code:	BTA

3 Name of the predicate Device(s)

- Medela® Basic, Median, Dominant, Vario Suction Pumps, by Medela Inc. K983552
- Versatile 1 Wound Vacuum System, by Blue Sky Medical Group Incorporated K042134

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4 Device Description

This notification for the **Medela® Vario** suction pumps is for a change in labeling and to include additional indications (for the **Medela® Vario 18 c/i** only). There have been no significant modifications or design changes to the currently cleared and marketed **Medela® Vario,** 510(k) No. K983552.
The only modifications relate to a change from lead acid to NiMH batteries and a more differentiated trade name - **Medela® Vario 8 and Vario 18** instead of **Medela® Vario** only (the number reflects the flow rate – 8 l/min or 18 l/min).

The **Medela® Vario** powered suction pump is a further innovative development of Medela's well-proven piston/cylinder system. With its QuatroFlex™ technology, the drive power is transferred to the four piston/cylinder modules by means of high-grade, flexible thin-films hinges. The required suction value is rapidly built-up. High suction performance and low weight are positive features of the **Medela® Vario**.

It is an AC or AC/DC-powered portable aspirator and incorporates in its medium sized housing an AC respectively DC-motor with a flat belt power transmission to the pistons and cylinders, an ON/OFF-switch, a vacuum gauge in kPa and mmHG and a self-bleeding membrane vacuum regulator.

The **Medela® Vario 18** "high vacuum" suction pump has a suction capacity of 18 liters per minute and a maximum vacuum up to -75 kPa (-563 mmHg). The pump is marked "*low flow – high vacuum*".

The **Medela® Vario 18 c/i** "medium vacuum" suction pump has a suction capacity of 18 liters per minute and a maximum vacuum up to -55 kPa (-413 mmHg). The pump is marked "*low flow – medium vacuum*".

The **Medela® Vario 8** "low vacuum" suction pump has a suction capacity of 8 liters per minute and a maximum vacuum up to -9 kPa (-68 mmHg). The pump is marked "*low flow – low vacuum*".

A variety of reusable and disposable accessories are available depending on the pump application. An overflow protection device (hydrophobic filter), connection tubing, electric cord and instruction manual and for the expanded indication of use for wound healing an accessory kit consisting of individually reviewed medical components.

5 Indications for use

The **Medela® Vario 8 and 18 Suction Pumps** are indicated for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from wounds or from a patient's airway or respiratory support system, either during surgery or at the patient's bedside.
These indications for use for the **Medela® Vario 8 and 18 Suction Pumps** are the identical to the ones mentioned for the original Medela® Vario Suction Pumps (K983552).

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The **Medela® Vario 18 c/i Suction Pump** is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. The device is also indicated for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids (including vomit) or infectious materials from a patient's airway or respiratory support system, either during surgery or at the patient's bedside.

Additional indication Wound Healing

It is intended to be used to create localized topical negative pressure when used with the Chariker-Jeter® wound sealing kit to promote wound healing and drainage of fluids and infected materials from the wound into a disposable or reusable canister.

Contraindications for Wound Healing Application

The **Medela® Vario 18 c/i** is contraindicated for the following reasons for Wound treatment:

- Presence of Necrotic tissue
- Untreated Osteomyeltitis
- Malignancy (except terminal patients for quality of life issues)
- Untreated malnutrition
- Use on exposed arteries, veins, or organs

The Blue Sky Medical Versatile 1 Wound Vacuum System (K042134) is **identical** to the **Medela® Vario 18 c/i** suction pump.

Precautions

- patients on anticogagulations or difficult hemostatis
- non-compliant patients

General Precautions for all indications for use

Health care provider must evaluate patient to insure that use of the **Medela® Vario 18 c/i** to promote wound healing is an appropriate use for the patient.

6 Summary of Technological Characteristics

The **Medela® Vario 8 and 18 suction pumps** are identical in construction and performance to the legally marketed device as submitted under FDA File Number K983552 - there are no technical differences which would raise new aspects regarding safety and effectiveness.
The only modifications relate to a change from lead acid to NiMH batteries and a more differentiated trade name - **Medela® Vario 8, 8c/i, 18 or 18 c/i** instead of **Medela® Vario** only (the number reflects the flow rate - 18 l/min).

The Blue Sky Medical Versatile 1 Wound Vacuum System (K042134) is **identical** to the **Medela® Vario 18 c/i** suction pump. Therefore the indications for use can be adopted.

7 Conclusion

According to the FDA Guidance „Deciding When to Submit a 510(k) for a Change to an Existing Device", the modifications mentioned above do not significantly affect the safety or effectiveness of the device (e.g. a significant change or modification in design, material, chemical composition, energy source or manufacturing process). All conclusions are made by the decision making process in accordance with this guidance document.

Based upon the information presented above and in this 510(k) submission, it is concluded that the proposed **Medela® Vario 18 c/i** powered suction pump is reliable, safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

Medela AG
% Mr. Scott Cohn
1101 Corporate Drive
Mchenry, Illinois 60050

Re: K061435
Trade/Device Name: Medela Vario Suction Pumps
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: May 22, 2006
Received: May 24, 2006

Dear Mr. Cohn:

This letter corrects our substantially equivalent letter of June 8, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061435

Device Name: Medela Vario Suction Pumps

Indications For Use:

The Medela Vario 8 and 18 Suction Pumps are indicated for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from wounds or from a patient's air-way or respiratory support system, either during surgery or at the patient's bedside.

The Medela Vario 18 c/i Suction Pump is indicated for patients who would benefit from a suctio device particularly as the device may promote wound healing. The device is also indicated for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids (includinç vomit) or infectious materials from a patient's airway or respiratory support system, either during surgery or at the patient's bedside.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K061435